REMARKS

This submission is in response to the non-final rejection issued by the USPTO on April 21, 2008. In order to advance the prosecution of this application, claim 1 was deleted and replaced with new claim 39. New claim 39 specifies the formulation must contain atorvastatin and this atorvastatin must have a mean particle size between 1 and 100 μm. Support for this limitation may be found on page 8, at lines 18-20. Claim 39 also specifies this formulation this formulation must be a tablet (see limitation c). Support for this limitation may be found thru-out the specification, including page 11, lines 24-28. This formulation must also contain one or more diluents having a particle size between 80 and 360 μm. Support for this limitation may be found on page 17, at lines 10-21. New claim 40 specifies the atorvastatin must be amorphous. Support for this limitation may be found on page 8, at lines 1-13. New claims 41-44 further clarify the particle size of the diluents. Support for this limitation may also be found on page 17.

REJECTION UNDER 35 USC 103

The claims were rejected under 35 USC 103 as being obvious over Wilson et al in view of Kerc et al. The USPTO has stated that Applicants claimed compositions contain the same components in the same configuration as the prior art. The USPTO asserts that Wilson shows the preparation of oral dosage forms of atorvastatin, prepared without a granulation step, containing less than 5% of an alkalizing agent. It is respectfully submitted that claim 39 and Wilson et al are not directed to the same composition, as will be explained below, and the rejection should be withdrawn.

New Claim 39 as drafted is directed to a dosage form that must be a tablet (i.e. a solid). Further this tablet must contain particulate atorvastatin, having a mean particle size between 1 and 100 μm. Further at least 50% of the excipients used to prepare the formulation (i.e. diluents) must also be particulate and have a mean particle size between 8 and 360 μm. New claim 39 is directed to a solid dosage form containing particulate atorvastatin.

Wilson et al does not disclose such a dosage form. As the USPTO noted in its communication of April 21st, Wilson discloses liquid formulations that may be "solidified" "to be used in hard capsules" (see page 3 of Wilson at lines 20-21). What the USPTO **did not note** was the phrase connecting "solidified" and "to be used in hard capsule". Wilson et al expressly states they should be solidified "**as taught herein**". Such disclosure occurs on page 8 of Wilson et al, at lines 9-20. Wilson et al states that if a solidified dosage form is desired, a high molecular weight polyethylene glycol is used as the solubilizing agent. This results in the formation of a gelled material, not a "particulate solid" as required by claim 39. Examples 21 and 39 of Wilson et al also show the production of such "gelled compositions."

This distinction is not a matter of semantics. As is shown in Example 3 of Applicant's specification, contacting atorvastain with water, at acidic pH's, leads to the formation of a significant amount of atorvastatin lactone, rather than the desired free acid. In Example 3, the formulation was prepared by wet granulation, without a base, and stored at elevated temperatures and humidity for 4 weeks. At the conclusion of the test, approximately 25% of the atorvastatin had been converted to the lactone. By contrast, Example 4 shows an identical formulation produced via direct compression. At the end of 4 weeks, only 0.12% of the atorvastain had converted to the lactone.

The USPTO also stated that Wilson et al shows the preparation of an atorvastatin formulation with out a base. This is factually incorrect. In fact, Wilson et al cautions against the preparation of such dosage forms. On page 10, beginning at line 4, Wilson teaches that bases must be incorporated into the formulation if the active ingredient is known to degrade in an acidic medium. Atorvastain is such a compound (the USPTO's attention is directed to the attached paper by Kearney et al. that discusses the impact of pH on atorvastatin lactone formation). Thus, Wilson teaches that bases must be incorporated into any atorvastatin formulation.

The quantity at base will vary with the dosage form. In a liquid, all of the molecules of the base are dissolved and are available to modulate the pH of the medium. In a "solidified dosage form" this is not the case. Substantial portions of the base will not be available to counteract the acid nature of many excipients and thus the quantity will rise exponentially as the water content of the formulation decreases.

Thus, the USPTO's premise that Wilson is disclosing the same composition as the claims is incorrect. Claims 39 is a solid in the form of a tablet. The atorvastatin is particulate, along with at least 50 w/w% of the diluent. Wilson does not disclose such a composition. It discloses a gel that should incorporate substantial quantities of base, if the active is atorvastatin.

The secondary reference, Kerc et al, does not cure the defects of Wilson et al. As discussed above, Wilson et al teaches that atorvastatin formulations must contain substantial quantities of base. Kerc et al's solid dosage forms (i.e. tablets) all contain substantial quantities of base, well in excess of the 5 w/w% specified in claim 1. In Example 1, on page 14, Kerc et al uses magnesium oxide to stabilize the formulation. It was present in the quantity of 10.4 w/w%. In example 2, sodium phosphate is the base and is present in the quantity of 45 w/w%. Similar results are depicted in Examples 3-6 on pages 15 of Kerc et al. Kerc et al did describe two comparative experiments, on pages 7 and 8, in which the bases were omitted from the formulation. Kerc et al concludes that these formulations were inferior due to the limited amount of atorvastatin found in the media after dissolution.

In summary, neither Wilson et al, nor Kerc et al disclose the same composition as claim 39. Claims 39 require a tablet containing less that 5 w/w% of an alkalizing additive. Wilson et al discloses a liquid or a gelled composition. Either will contain substantial quantities of base to preclude lactone formation, with the exact amount varying inversely with water content. Kerc discloses tablets containing well in excess of 5 w/w% of an alkalizing agent.

Withdrawal of the rejections of record and reconsideration is respectfully requested. If the USPTO feels that minor amendments are required to place the case in condition for allowance, the undersigned invites a phone call to discuss such proposals.

A prompt and favorable response is earnestly solicited.

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